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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,893	10/27/2000	Morey Kraus	07588/008001	5973

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EXAMINER	
FALK, ANNE MARIE	

ART UNIT	PAPER NUMBER
1632	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/698,893	KRAUS ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-13,15,19-25,27,29-33,35,37 and 41-44* is/are pending in the application.

4a) Of the above claim(s) *12,22-24,42 and 43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-11, 13, 15, 19-21, 25, 27, 29-33, 35, 37, 41 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 January 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed January 16, 2007 has been entered. Claims 1-3, 5, 6, 8-11, 13, 15, 19, 25, 27, 29-33, 37, and 44 have been amended. Claims 4, 14, and 16 have been cancelled.

Accordingly, Claims 1-3, 5-13, 15, 19-25, 27, 29-33, 35, 37, and 41-44 remain pending in the instant application.

The amendment filed January 18, 2005 was not entered due to the deficiency noted in the Notice mailed January 4, 2007. The remarks filed January 18, 2005 (hereinafter referred to as "the response") are considered herein.

Claims 12, 22-24, 42, and 43 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction requirement in the response filed 9/16/02.

Accordingly, Claims 1-3, 5-11, 13, 15, 19-21, 25, 27, 29-33, 35, 37, 41, and 44 are examined herein.

The objection to Claims 37 and 41 for encompassing non-elected subject matter is withdrawn in view of the amendment to Claim 37.

The objection to Claim 16 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, is withdrawn in view of the cancellation of the claim.

The double patenting warning pertaining to Claim 4 is withdrawn in view of the cancellation of Claim 4.

The rejection of Claims 37 and 41 under 35 U.S.C. 112, second paragraph, as indefinite in their recitation of "plurability", is withdrawn in view of the amendment to Claim 37 to now recite "plurality."

Drawings

The drawings filed January 18, 2005 (Figures 1-10) are not accepted. The drawings are objected to because the replacement sheets are not labeled "Replacement Sheet" in the page header. Pursuant to 37 CFR 1.121(d), each drawing sheet submitted after the filing date of an application must be identified as either "Replacement Sheet" or "New Sheet." As per 37 CFR 1.84(c), replacement sheets should be labeled "Replacement Sheet" in the page header so as not to obstruct any portion of the drawing figures. Any changes to an application drawing must be in compliance with 37 CFR 1.84(c).

See the guidance provided at pages 2-3 of the prior Office Action mailed July 13, 2004

Corrected drawings are required in reply to this Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Objections

Claim 13 remains objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 13 requires that the improvement result in repair of central nervous system damage caused by said stroke. This is not further limiting because Claims 1 and 2 both require an improvement in function of the central nervous system. In order for a functional improvement to be observed, it would necessarily have to include repair, as broadly defined. Given its broadest reasonable interpretation, the term "repair" includes functional improvement as well as structural repair. At page 15 of the response, Applicants assert that Claim 13 further limits the subject matter of Claims 1 and 2 by specifying that the "improvement" in central nervous system functioning indicated in Claims 1 and 2 occurs by repairing the damage done to brain tissues as a result of the stroke. Applicants go on to assert

that, in this embodiment, the method results in the re-establishment of communication between, e.g., two or more neurons (e.g., by regrowth of axons), rather than the generation of new neurons. Applicants further assert that this is contrasted with the mode of improvement recited in Claim 15, which is directed to an improvement that results due to regeneration of brain tissues at the site of the stroke (i.e., new tissue growth). Applicants conclude that Claims 13 and 15 are directed to two distinct mechanisms by which the improvement is effected, and the limitations serve to further limit the subject matter of Claims 1 and 2.

Applicants are incorrect in asserting that Claim 13 is directed to the embodiment where the method results in the re-establishment of communication between two or more neurons by regrowth of axons, rather than the generation of new neurons because the language of Claim 13 only requires "repair of central nervous system damage caused by said stroke." Given its broadest reasonable interpretation, the term "damage" may refer to the structural or functional damage caused by said stroke. Therefore, the term "repair" includes functional improvement as well as structural repair, given its broadest reasonable interpretation. Claims 1 and 2 already require functional improvement and therefore the limitation of Claim 13, referring to "repair of central nervous system damage caused by said stroke."

While Claim 15 is not at issue here, Applicants attempt to distinguish Claim 13 from Claim 15 by suggesting that Claim 13 is directed to regrowth of axons, while Claim 15 is directed to regeneration of brain tissue, involving new tissue growth. This is not found convincing because the term "regeneration" is routinely used to refer to axonal regeneration/regrowth in the absence of the appearance of new neurons and regrowth of axons does generate new tissue (see Grill and Tuszynski, Axonal Responses to Injury, in CNS Regeneration: Basic Science and Clinical Advances, 1999). Thus, the regrowth of axons **is** "regeneration of central nervous system tissue damaged by said stroke" as recited in Claim 15. Therefore, this argument is not convincing with regard to the suggested interpretation of Claim 13 because Claim 13 does not refer to the regrowth of axons and therefore does not require regrowth of axons. Claim 13 **only**

requires that "the improvement results in repair of central nervous system damage cause by said stroke" and therefore does not require anything more than the functional improvement already recited in Claims 1 and 2. Thus, the language of Claim 13 fails to further limit the subject matter of Claims 1 and 2.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claims 1-3, 5-11, 13, 15, 19-21, 25, 27, 29-33, 35, 37, 41, and 44, and are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amended claims include new matter.

MPEP 2163.03 provides that an amendment to the claims or the addition of a new claim must be supported by the description of the invention in the application as filed. *In re Wright*, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989). Applicants should specifically point out the support for any amendments made to the claims. MPEP 2163 states that new or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) and *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972).

Independent claims 1, 2, 37, and 44 have been amended to recite "wherein said CD34+/-, Lin- cells in said sample are enriched relative to CD34+/-, Lin- cell present in a mononuclear cell fraction of

umbilical cord blood," but the newly added claim limitation introduces new matter. At page 13 of the response, Applicants allege that support for this new limitation is found in the specification at page 5, lines 16-18 and in Example 5 of U.S. Patent No. 5,925,567. However, the cited section of the instant specification only refers putting cord blood cells through a selection procedure as described in U.S. Patent No. 5,925,567 and Example 5 of U.S. Patent No. 5,925,567 only describes a selection procedure for the selection of **CD34+** cells. It does not describe the selection of CD34+/-, Lin- cells as presently recited in the claims. Therefore, the cited sections do not provide support for the presently claimed subject matter wherein the method involves the preparation and use of a sample enriched for CD34+/-, Lin- cells relative to a mononuclear cell fraction of umbilical cord blood. The specification does not contemplate preparing a sample of cells wherein the sample is enriched for CD34+/-, Lin- cells relative to CD34+/-, Lin- cells present in a mononuclear cell fraction of umbilical cord blood. Applicants have not pointed to appropriate support in the as-filed specification for the newly added claim limitation. The Examiner has reviewed the specification and finds no support in the as-filed specification for the cell fraction now recited in the claims. Thus, the as-filed specification does not contemplate or describe the CD34+/-, Lin- enriched cell fraction as presently recited in the claims.

Thus, the amended claims include new matter.

Written Description

Claims 1-3, 5-11, 13, 15, 19-21, 25, 27, 29-33, 35, 37, 41, and 44 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants are referred to the final guidelines on written description published

January 5, 2001 in the Federal Register at Volume 66, Number 4, pp. 1099-1111 (also available at www.uspto.gov).

Applicants are reminded that the written description requirement is severable from the enablement requirement. *In re Barker*, 559 F.2d 588, 194 USPQ 470 (CCPA 1977), *cert.* denied, 434 U.S. 1064 (1978); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991) (While acknowledging that some of its cases concerning the written description requirement and the enablement requirement are confusing, the Federal Circuit reaffirmed that under 35 U.S.C. 112, first paragraph, the written description requirement is separate and distinct from the enablement requirement and gave an example thereof). An invention may be described without the disclosure being enabling (e.g., a chemical compound for which there is no disclosed or apparent method of making), and a disclosure could be enabling without describing the invention (e.g., a specification describing a method of making and using a paint composition made of functionally defined ingredients within broad ranges would be enabling for formulations falling within the description but would not describe any specific formulation). See *In re Armbruster*, 512 F.2d 676, 677, 185 USPQ 152, 153 (CCPA 1975).

The Guidelines for Written Description specifically state that "[t]he claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art" (Federal Register, Vol. 66, No. 4, page 1105, column 1).

The cell composition used for transplantation is an essential element of the claimed invention. The specification states that the cells administered may be "CD34+/-, Lin- cells separated from cord blood" (page 6, lines 16-17). The specification further asserts in the Example section that "CD34+/-, Lin- cells" were administered to the rats. The specification relies on U.S. Patent No. 5,925,567 for teaching how to obtain "CD34+/-, Lin- cells" (page 6, lines 21-23). In the Example section, the specification states that the "CD34+/-, Lin- cells" used in the example "were selected from a sample of fresh cord blood cells

using the procedure described in Example 5 of U.S. Patent No. 5,925,567" (page 10, lines 9-11). The specification does not further describe "CD34+/-, Lin- cells," nor does it define the meaning of the designation "CD34+/-". While one of skill in the art would understand that "Lin-" cells do not express the Lin marker, one of skill in the art would not understand the meaning of "CD34+/-". The term is not defined in the specification and is not conventional in the art. Example 5 of U.S. Patent No. 5,925,567 does not describe the preparation of "CD34+/-, Lin- cells." Example 5 describes the preparation of CD34- cells from the mononuclear fraction of umbilical cord blood. The patent does not describe "CD34+/-, Lin- cells."

Given that the specification discloses that the cell composition used in the Example comprises "CD34+/-, Lin- cells," one of skill in the art would not know the identity of the cell composition that produced the result described therein. Further, given the limited details for obtaining the cell composition used in the Example of the specification, the skilled artisan would not know how to obtain the requisite cell composition for transplantation. This limited information is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of the cell compositions required for use in the claimed method, at the time the application was filed. Furthermore, the instant specification does not place the public in possession of the cell compositions. Thus, it is concluded that the written description requirement is not satisfied for the claimed methods of cell transplantation.

At page 16, paragraph 2 of the response, Applicants assert that the term "CD34+/-, Lin-" is a shorthand designation used by those skilled in the art to specify the presence of absence of CD34 and the absence of lineage-specific markers (Lin-). Applicants assert that both CD34-positive and CD34-negative cell populations are present in the target population. Applicants are reminded that Attorney argument cannot take the place of actual evidence. No evidence is presented to support the assertions made regarding the meaning of the term as used by those skilled in the art. See MPEP § 2145 and 716.01(c)(II). The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*

145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding the meaning of terminology as used in the art.

Enablement

Claims 1-3, 5-11, 13, 15, 19-21, 25, 27, 29-33, 35, 37, 41, and 44 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to a method of causing an improvement in function of the central nervous system of a subject having impaired central nervous system function by administering "an aliquot of CD34+/-, Lin- cells." The cells may be derived from umbilical cord blood or other blood sources.

The specification discloses an example at pages 10-13 where male Sprague Dawley rats were subjected to an MCA occlusion and subsequently received an injection of "CD34+/-, Lin- stem cells" directly into the ischemic region of the brain. Some modest improvement was observed in two of the behavioral tests that the animals were subjected to following treatment; specifically, the forelimb placing test and the hindlimb placing test. No improvement was observed in 3 other behavioral tests that the animals were subjected to (i.e., swinging, cylinder, or paw reaching tests).

While the Example is limited to transplantation of a specific cell type (CD34+/-, Lin-) isolated from a sample of fresh cord blood, for the reasons discussed herein above, the skilled artisan would not know what is meant by "CD34+/-" and would not be able to obtain the cells referred to in the Example section. Furthermore, the Example does not specify from which animal species the cells were isolated, although it does state that cyclosporin was administered to the rats. Furthermore, the "aliquot of CD34+/-

, Lin- cells" is not disclosed as being a homogeneous cell population, and is therefore understood to comprise a variety of other cell types.

The state of the art is such that very little is known about the cell types that can be used to restore neurological function. One of the lingering questions in the field of stem cell research relates to the stage of differentiation of stem cells useful for transplantation and whether the same stage will be useful for all transplantation applications, or vary on a case-by-case basis (see p. ES-8, column 1 of Stem Cells: Scientific Progress and Future Research Directions, June 2001).

In a review of the state of the art of stem cell technology, the National Institutes of Health acknowledge the potential usefulness of stem cells in theraeutic transplantation and the possible development of therapeutic protocols in the future (see Stem Cells: Scientific Progress and Future Research Directions, June 2001). However, the review also illustrates that there are numerous and significant obstacles that must be overcome. As such, the asserted utility of the present invention, directed to using the claimed methods in therapeutic transplantation to treat stroke constitutes a credible utility, albeit one that is not enabled by the instant specification. The instant rejection therefore is not for lack of utility, but rather for lack of enablement for the asserted utility. For the reasons discussed herein, the specification does not teach how to use the claimed methods to produce a therapeutic effect nor does it adequately teach how to practice the claimed method, which covers transplantation of a variety of cell types, as well as combined administration of cells and growth factors.

The specification fails to provide an enabling disclosure for the method of cell-based therapy because methods of transplantation of stem cells, precursor cells, and neural tissue into the CNS are not routinely successful and the specification does not offer adequate guidance to overcome the unpredictability in the art to enable one skilled in the art to practice the claimed method over the full scope to derive a therapeutic benefit in a diseased animal. The specification teaches that the only use for the claimed method of transplantation is to produce a therapeutic effect, but the specification does not

adequately teach how to carry out the claimed methods to produce such an effect. Jackowski et al. (1995) details the limitations and unpredictability associated with transplantation of neural tissue. At page 311, column 1, paragraph 2, the reference discusses barriers to successful transplantation of neural tissue, notably the presence of molecules that actively inhibit the regeneration of mammalian CNS axons.

The specification fails to provide an enabling disclosure for producing a therapeutic effect using the claimed methods of therapeutic transplantation because the specification does not provide **specific guidance** for transplanting appropriate cell compositions or for the combined administration of various cells and growth factors. In unpredictable arts, it is the specification itself that must provide the novel teachings for carrying out the claimed methods therapeutically. The working example is limited to transplantation of a specific cell type (CD34+/-, Lin-) isolated from a sample of fresh cord blood, into a rat that serves as a stroke model, but the specification does not adequately describe the cell type or its method of preparation. The specification contemplates that "cells of the invention" can be used to treat a wide variety of neurodegenerative diseases, including stroke, Huntington's disease, Parkinson's disease, Alzheimer's disease, ALS, multiple sclerosis , Tay-Sacks, and cerebral palsy (page 4, lines 8-9). However, the elected invention is limited to methods of treating stroke. Accordingly, the specification must teach how to practice the full scope of the claimed methods of transplantation to produce a therapeutic effect in a patient having suffered from a stroke. The specification fails to provide specific guidance relating to the cell compositions required to provide a therapeutic benefit for stroke.

The court has recognized that physiological activity is unpredictable. *In re Fisher*, 166 USPQ 18 (CCPA 1970). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved. *In re Fisher*, 166 USPQ 18 (CCPA 1970).

It is not to be left up to the skilled artisan to figure out how to make the necessary starting materials and then to figure out how to use them to produce the biological effects as recited in the claims.

The courts held that the disclosure of an application shall inform those skilled in the art how to use applicant's claimed invention, not how to **find out** how to use it for themselves. *In re Gardner et al.* 166 USPQ 138 (CCPA 1970). This specification only teaches what is intended to be done and how it is intended to work, but does not actually teach how to do that which is intended.

Given the limited working examples, the limited guidance provided in the specification, the broad scope of the claims with regard to the various cell compositions to be transplanted and the combinations of cells and growth factors to be administered, and the unpredictability for producing a therapeutic effect upon transplantation of stem cells or precursor cells, undue experimentation would have been required for one skilled in the art to practice the claimed methods of transplantation to produce a therapeutic effect in a stroke patient.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-11, 13, 15, 19-21, 25, 27, 29-33, 35, 37, 41, and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-11, 13-16, 19-21, 25, 27, 29-33, 35, and 44 are indefinite in their recitation of "CD34+/-, Lin- cells" because the term "CD34+/-" is not defined in the specification and is not conventional in the art. Thus, it is unclear what the "CD34+/-" designation means. It is therefore unclear what cell type is to be used in the claimed method.

Claim 14 is indefinite in its recitation of "central nervous system disease caused by said stroke" because stroke does not **cause** CNS disease. Stroke is typically a **result of** cerebrovascular disease.

Claims 25 and 31 are indefinite in their recitation of "intercerebrally" because one of skill in the art would understand the term to refer to brain tissue or fluid-filled space that lies **between** the two

cerebral hemispheres, but the specification does not define the term "intercerebrally" as it is being used in the context of the claims. Thus, it is unclear what brain structures would be considered to lie between the two cerebral hemispheres. Nothing in the specification suggests injecting the cell composition into the cerebrospinal fluid that lies between the two cerebral hemispheres. The metes and bounds of the claims are not clearly set forth.

Claims 25 and 31 are indefinite in their recitation of "intercerebrally, intracisternally, intracebroventricularly" because Claims 1 and 2, from which Claims 25 and 31 depend, are already limited to administering the cells "directly to the site of said stroke." The "site of said stroke" would necessarily be located within the brain tissue and therefore would not be located in the fluid-filled spaces such as the ventricles.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5-11, 13, 15, 19-21, 25, 27, 29-33, 35, 37, 41, and 44 stand rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication No. 2002/0028510 A1 (Sanberg et al.; published March 7, 2002; filed March 9, 2000), as evidenced by Rosu-Myles et al. (2000, Stem Cells 18: 374-381).

The claims are directed to a method of causing an improvement in function of the central nervous system of a subject having impaired central nervous system function resulting from a stroke.

Sanberg et al. (2000) disclose a method for treating stroke by administering umbilical cord blood cells. Claim 39 recites "a method of treating a patient with a neurodegenerative disease comprising administering an effective number of neural cells in umbilical cord blood or a mononuclear fraction therof to said patient." Claim 40 specifically recites treating ischemia. Claim 64 recites "a method of treating a patient in need thereof for a neurodegenerative disease other than amyotrophic lateral sclerosis, said method comprising administering an effective amount of human umbilical cord blood or a mononuclear cell fraction thereof to said patient." Claim 65 specifically recites treating ischemia. The disclosure explicitly contemplates using the method of the invention to treat stroke (paragraphs [0042], [0054], [0065], and paragraphs {0161] through [0233]). The reference discloses significant functional recovery in a rat stroke model (paragraph [0231]).

The reference of Sanberg et al. inherently discloses administration of a cell composition comprising Lin- cells, as recited in the claims, because human cord blood cells inherently comprise Lin- cells, as evidenced by Rosu-Myles et al.

Thus, the claimed invention is disclosed in the prior art.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action

is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER